

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 7 is confusing because "[t]he nucleic acid chip" lacks proper antecedent basis. Correction is required.

B) Claims 14-16 are confusing because independent claim 14 lacks typical connecting language such as "comprising" or "consisting of" such that the scope of the claimed method can be determined. Further, "the marker" in claim 14 lacks proper antecedent basis. Correction is required.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 8, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Abrams et al. (US 6,238,927).

Claims 1-3 are drawn to a partially double-stranded nucleic acid comprising a first and second single-stranded nucleic acid having partial complementarity and hybridized together. Claim 7 is drawn to a chip comprising such a nucleic acid fixed on a substrate, and claims 8 and 14 are drawn to methods of using such a nucleic acid to detect a target nucleic acid.

Abrams et al. disclose such a nucleic acid, a support to which such a nucleic acid is fixed, and methods of using such a nucleic acid to detect a target nucleic acid (see Figs. 1 and 2, and columns 2-12).

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams et al. in view of Diamond et al.

This claim is drawn to the nucleic acid as described and rejected above, wherein the first and second single-stranded nucleic acids each have a member of donor-acceptor fluorescent dye pair.

The teachings of Abrams et al. are described above.

Abrams et al. do not teach a nucleic acid comprising a donor-acceptor fluorescent dye pair.

Diamond et al. disclose a partially double-stranded nucleic acid for displacement assays, wherein each component single-stranded nucleic acid comprises a member of a donor-acceptor fluorescent dye pair (see Figs. 3A-3C and column 21, lines 15-68).

One of ordinary skill in the art would have been motivated to modify the single fluorophore detection means in the probe and method of Abrams et al. by using a donor-acceptor dye pair because the benefits of such a dye pair were disclosed by Diamond et al. in a similar probe displacement assay. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed nucleic acid.

5. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams et al. in view of either of Bagwell (US 5,607,834) or Becker et al. (US 6,361,945).

These claims are drawn to the nucleic acid as described and rejected above, wherein the first and second single-stranded nucleic acids are connected by a linker.

The teachings of Abrams et al. are described above.

Abrams et al. do not teach a nucleic acid comprising a linker.

Bagwell discloses a partially double-stranded nucleic acid for displacement assays, wherein the two single-stranded components are linked by a nucleic acid linker (see Figs. 1-2 and column 4, line 45 to column 5, line 9).

The same disclosure is also included in Becker et al. (see Fig. 3A and column 16, lines 19-27).

One of ordinary skill in the art would have been motivated to modify the partially double-stranded probe of Abrams et al. by using a nucleic acid linker to connect the two single-stranded components because such a linker was disclosed by both Bagwell and Becker et al. in a similar probe displacement assay. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed nucleic acid.

6. Claims 9, 10, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams et al. in view of Kim et al. (JACS 2002).

These claims are drawn to the nucleic acid detection method as described and rejected above, wherein contacting is in the presence of an amine or quaternary ammonium salt, or a cationic polymer.

The teachings of Abrams et al. are described above.

Abrams et al. do not teach the use of an amine or quaternary ammonium salt, or a cationic polymer, to facilitate a strand displacement assay.

Kim et al. disclose the use of a cationic polymer to facilitate a strand displacement assay. They also disclose that it was known in the art to do so with a quaternary ammonium salt. See entire document on pages 12676-12677, especially the second paragraph.

One of ordinary skill in the art would have been motivated to modify the probe displacement assay of Abrams et al. by using a quaternary ammonium salt or a cationic polymer because Kim et al. taught that these compounds facilitated strand displacement reactions. Thus, the use of these compounds would have been expected to improve the assay of Abrams et al. which is based on strand displacement. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams et al. in view of Eastman et al. (US 5,827,648).

These claims are drawn to the nucleic acid detection method as described and rejected above, wherein a sequence mismatch is detected.

The teachings of Abrams et al. are described above.

Abrams et al. do not teach detection of a sequence mismatch in their displacement assay.

Eastman et al. disclose that detection of a sequence mismatch using nucleic acid hybridization probes was conventional in the art (see column 1, lines 40-50).

One of ordinary skill in the art would have been motivated to apply the probe displacement assay of Abrams et al. to detect a sequence mismatch because detecting sequence mismatches was a conventional application of nucleic acid probe technology (Eastman et al.). It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed method.

8. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams et al. in view of Eastman et al., and further in view of Kim et al.

These claims are drawn to the nucleic acid detection method as described and rejected above, wherein contacting is in the presence of an amine or quaternary ammonium salt, or a cationic polymer.

The teachings of Abrams et al. and Eastman et al. are described above.

These references do not teach the use of an amine or quaternary ammonium salt, or a cationic polymer, to facilitate a strand displacement assay.

Kim et al. disclose the use of a cationic polymer to facilitate a strand displacement assay. They also disclose that it was known in the art to do so with a quaternary ammonium salt. See entire document on pages 12676-12677, especially the second paragraph.

One of ordinary skill in the art would have been motivated to modify the probe displacement assay as suggested by the combination of Abrams et al. and Eastman et al. by using a quaternary ammonium salt or a cationic polymer because Kim et al. taught that these compounds facilitated strand displacement reactions. Thus, the use of these compounds would have been expected to improve the assay, which is based on strand displacement. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

9. No claims are free of the prior art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

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